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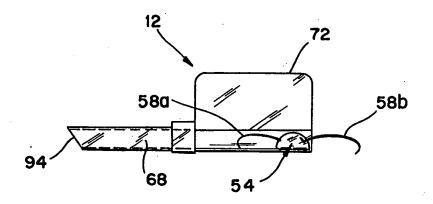
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### (54) Title: INTRAOCULAR LENS MICROCARTRIDGE

#### (57) Abstract

This invention is a surgical device (10) for implantation of deformable intraocular lens (54) into the eye through a relatively small incision made in the ocular tissue including a holder (12) with receiver (13) for a lens holder; a lens holder (12) for a surgical device for implantation of deformable intraocular lens (54) into the eye including a split tubular member (12) having a fixed tubular portion (70), and a moveable tubular portion (72) connected together at a hinge (82); and a method for implantation of deformable intraocular lens into the eye using the above described surgical devices.



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### INTRAOCULAR LENS MICROCARTRIDGE

## **RELATED APPLICATION(S)**

This application is a continuation-in-part application of U.S. patent application Serial No. 07/953,251 filed on September 30, 1992, now abandoned.

### FIELD OF THE INVENTION

This invention relates to an improved microcartridge for use with devices for the surgical implantation of deformable intraocular lenses into the eye.

## BACKGROUND OF THE INVENTION

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Intraocular lenses have gained wide acceptance in replacement of human crystalline lenses after a variety of cataract removal procedures. The human crystalline lens is generally recognized to be a transparent structure having a thickness of about five (5) millimeters and a diameter of about nine (9) millimeters. The lens is suspended behind the iris by zonula fibers which connect

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the lens to the ciliary body. A lens capsule surrounds the lens, the front portion of the capsule being commonly known as the anterior capsule and the back portion commonly known as the posterior capsule.

Numerous procedures for the removal of cataracts have been developed in which the lens is removed from the eye and replaced by an artificial lens implant. The extraction procedure may generally be categorized as intracapsular (in which the lens is removed together with the lens capsule) and extracapsular (in which the anterior capsule is removed with the lens, and the posterior capsule is left intact).

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Since Ridley implanted the first artificial lens in about 1949, the problems associated with cataract extraction and lens implantation have received a great deal of attention from ophthalmic surgeons. Various types of artificial lenses have been proposed, and appropriate surgical procedures have been developed which strive to reduce patient discomfort and to reduce postoperative complications. Reference is made in this connection to Pseudophakos by N. Jaffe et al.; "History of Intraocular Implants" by D.P. Choyce (Annals of Ophthalmology, October 1973); U.S. Patent No. 4,251,887 issued to Anis on February 24, 1981; U.S. Patent No. 4,092,743 issued to Kelman on November 8, 1977; "Comparison of Flexible Posterior Chamber Implants", presented at the American Intraocular Implant Society Symposium April 23, 1982, by Charles Berkert, M.D.; and "the Simcoe Posterior Lens" (Cilco, Inc. 1980); U.S. Patent No. 4,573,998 issued to Mazzocco on March 4, 1986, and U.S. patent application Ser. No. 400,665 for "Improved Fixation System for Intraocular Lens Structures", filed July 22, 1982, U.S. Patent No. 4,702,244 issued to Mazzocco on October 27, 1987; and U.S. Patent No. 4,715,373 issued to Mazzocco et al. on December 29, 1987, which disclosures are hereby incorporated by reference.

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Of particular interest in the context of the present invention is the development of surgical techniques requiring relatively small incisions in the ocular tissue for the removal of cataracts as disclosed in U.S. Patent No. 4,002,169 and U.S. Patent No. 3,996,935. A number of skilled artisans have disclosed intraocular lens structures comprising an optical zone portion generally made of rigid materials such as glass or plastics suitable for optical use.

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However, one of the principal disadvantages of the conventional rigid intraocular lens is that implantation of the lens requires large incisions in the ocular tissue. This type of surgical procedure leads to a relatively high complication rate, among other disadvantages. For instance, the serious dangers associated with implantation of a rigid lens structure include increased risk of infection, retinal detachment, and laceration of the ocular tissue, particularly with respect to the pupil.

Accordingly, those skilled in the art have recognized a significant need for surgical tools for implantation of deformable intraocular lens structures which afford the clinical advantages of using relatively small incision techniques, which provide a safer and more convenient surgical procedure. In particular, those skilled in the art of deformable intraocular lenses and methods and devices for implantation, have also recognized a significant need for surgical tools which do not require widening of the wound made in the ocular tissue during or after implantation, but will deform the intraocular lens to a predetermined cross section in a stressed state and which allow the ophthalmic surgeon to inspect the lens prior to implantation without manipulation in the eye. The present invention fulfills these needs.

The present invention was derived by improving the methods and devices in the above-identified patents, specifically the methods of U.S. Patent No. 4,573,998 and the devices of U.S. Patent No. 4,702,244.

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## SUMMARY OF THE INVENTION

An object of the present invention is to provide an improved microcartridge for use with devices for surgical implantation of deformable intraocular lenses.

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Another object of the present invention is to provide an improved lens microcartridge comprising a lens holding portion and nozzle having a through bore with a pair of opposed groovesa lens holding portion in covice including a lens holder, which can be loaded with a deformable intraocular lens, and then inserted into a holder having means for implanting the lens.

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A further object of the present invention is to provide a surgical device including a lens holder define by a microcartridge comprising a lens holding portion in combination with a nozzle for implanting the lens.

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A still further object of the present invention is to provide a lens holding microcartridge for receiving a lens comprising a split tubular member having a fixed portion with an extension, and a moveable portion with an extension for opening and closing the microcartridge, which extensions prevent rotation between the microcartridge and holder when installed in the holder.

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An even further object of the present invention is to provide a lens holding microcartridge having a nozzle provided with slots for rotating the lens as it exits the nozzle.

An object of the present invention is to provide a surgical device including a lens holder and a holder for the lens holder, the holder comprising a receiver for the lens holder and a plunger for inserting the lens.

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Another object of the present invention is to provide a holder defined by a cylindrical tubular member with an opening through the wall of the tubular member defining a receiver for the lens holder, and a plunger having a tip for contacting with and moving a lens contained in the lens holder.

A further object of the present invention is to provide a plunger with a faceted tip that provides clearance for a trailing haptic in a passageway through the lens holder during the implantation process to prevent damage to the trailing haptic.

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An even further object of the present invention is to provide a plunger having a tip with a concave conical surface at the tip thereof for grabbing the lens during the implantation process.

An object of the present invention is to provide improved methods of implanting deformable intraocular lenses;

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Another object of the present invention is to provide a method including loading a deformable intraocular lens into a lens holder having an implantation nozzle, condensing the intraocular lens within the lens holder, and implanting the lens into the eye.

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The present invention concerns a system including methods and devices for implantation of intraocular lenses into the eye.

The surgical device according to the present invention includes the combination of a lens holder and a holder for the lens holder. The preferred lens holder comprises the combination of a lens receiver and an implantation nozzle. The lens receiver is preferably defined by a microcartridge comprising a split tubular member having a fixed tubular portion with an extension connected to a moveable tubular portion with an extension at a hinge. This configuration allows the microcartridge to be opened to accept a deformable intraocular lens, and closed to condense the lens into the passageway. The split tubular portion is connected to a nozzle with a continuous passageway passing through the tubular

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member and the nozzle.

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The lens holder is inserted into a holder having means for driving or manipulating the lens from the lens holder into the eye. In the preferred embodiment, the holder is provided with a plunger for driving the lens from the lens holder into the eye. Further, the holder is configured to receive a microcartridge having a nozzle.

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The preferred holder includes means to prevent the microcartridge from rotating within the holder, and means for preventing the plunger from rotating within the holder. The means for preventing rotation of the microcartridge within the holder can be define by providing the microcartridge with one or more extensions that cooperate with the opening of the receiver of the holder to prevent rotation. The means for preventing the plunger from rotating within the holder can be defined by providing the plunger and a sleeve within the holder with a particular cross-sectional shape that prevents rotation, for example, a half-circle shape.

The preferred holder includes a plunger with a threaded cap cooperating with a threaded sleeve of the holder body for dialing the plunger forward within the holder for precise and accurate movement of the lens during the implantation process. The holder is configured so that the plunger can be moved a predetermined distance by sliding motion within the holder body followed by engagement of the threaded cap of the plunger with the threaded sleeve of the holder body to continue the forward progress of the plunger tip.

The preferred plunger tip is defined by a faceted tip having various surfaces for moving and manipulating the lens from the lens holder and within the eye. The tip is designed to provide a clearance between the tip and the inner surface of the passageway through lens holder to accommodate the trailing haptic and prevent damage thereto. Once the lens is inserted into the eye, the tip can be used to push and rotated the lens into proper position within the eye.

A method according to the present invention includes lubricating the surface of a deformable intraocular lens with a surgically compatible lubricant, and loading the lens into a microcartridge in the opened position. The microcartridge is closed while condensing the lens by a folding action into a shape so that it can be forced through the passageway in the microcartridge. The microcartridge is inserted into the holder with the plunger retracted.

The plunger is moved forward in a sliding manner by pushing the plunger forward while holding the holder body still. This action forces the lens from the tubular member portion of the microcartridge into the nozzle portion. At this point the threads of the threaded end cap of the plunger engage with the threads of the threaded sleeve. The threaded end cap is rotate slightly to engage the threads. The device is now ready for the implantation process.

The nozzle of the microcartridge is placed through a small incision in the eye. The threaded end cap of the plunger is rotated or dialed to further advance the lens forward through the nozzle and into the eye. The threaded end cap is further dialed to exposed the tip of the plunger within the eye and push the lens into position. The tip can be used to also rotate the lens within the eye for positioning of the haptics.

#### BRIEF DESCRIPTION OF THE DRAWINGS

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Figure 1 is a perspective view of one embodiment of device according to the present invention with a lens holding microcartridge positioned in the device for implantation of deformable lens structures for placement in the eye.

Figure 2 is a perspective view of the surgical device depicted in Figure 1 with the plunger retracted, and with the lens holding microcartridge removed.

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Figure 3 is a side view of the device depicted in Figure 2, with the plunger in the extended position.

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Figure 4 is a side elevational view of the device shown in Figure 1.

Figure 5 is a detailed longitudinal cross-sectional view of the device shown in Figure 4.

Figure 6 is a detailed transverse cross-sectional view of the device, as indicated in Figure 5.

Figure 7 is a detailed end view of the device, as indicated in Figure 5.

Figure 8 is an enlarged detailed left side elevational view of the tip of the plunger in the spacial orientation as shown in Figure 1.

Figure 9 is an enlarged detailed end view of the tip shown in Figure 8.

Figure 10 is an enlarged detailed top planar view of the tip of the plunger.

Figure 11 is an enlarged detailed right side elevational view of the tip of the plunger in the spacial orientation, as shown in Figure 4.

Figure 12 is an enlarged detailed bottom view of the tip of the plunger in the spacial orientation, as shown in Figure 1.

Figure 13 is a perspective view of a lens for use in the present invention.

Figure 14 is a perspective view of another type of lens for use in the present invention.

Figure 15 is a side view of the lens shown in Figure 13.

Figure 16 is a perspective view of the lens holding microcartridge in the open position to allow a lens to be loaded therein.

Figure 16A is another perspective view of the lens holding microcartridge in the open position.

Figure 17 is a rear end elevational view of the lens holding microcartridge in the open position.

Figure 18 is a front end elevational view of the lens holding microcartridge in the open position.

Figure 19 is a rear end elevational view of the lens holding microcartridge in the closed position.

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Figure 20 is a front end elevational view of the lens holding microcartridge in the closed position.

Figure 20A is a detailed end view of the nozzle showing three (3) slots of different length equally spaced about the circumference of the tip.

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Figure 20B is a detailed perspective view of the tip showing the three (3) slots of different length.

Figure 20C is a detailed side view showing the beveled tip.

Figure 21 is a top planar view of the lens holding microcartridge in the open position.

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Figure 22 is a side elevational view of the lens holding microcartridge in the closed position.

Figure 23 is a rear end elevational view of the lens holding microcartridge in the closed position.

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Figure 24 is a broken away side view of the device showing the lens holding microcartridge in relationship to the plunger in the retracted position.

Figure 25 is a broken away side view of the device showing the lens holding microcartridge in relationship to the plunger in a partially extended position.

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Figure 26 is a broken away side view of the device showing the lens holding microcartridge in relationship to the plunger in a fully extended position.

Figure 27 is a perspective view showing the device positioning a deformable intraocular lens within the eye.

Figure 28 is a cross-sectional view of an eye showing the positioning of the deformable intraocular lens into position in the eye by the surgical device.

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Figure 29 is a cross-sectional view of an eye showing the positioning of the deformable intraocular lens into a different position in the eye by the surgical device.

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Figure 30 is a side elevational view of an alternative embodiment of the lens holding microcartridge provided with a beveled tip.

Figure 31 is a rear end elevational view of another alternative embodiment of the lens holding microcartridge provided with grooves in the passageway to facilitate folding the cartridge in an open position.

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Figure 32 is a rear end elevational view of another alternative embodiment of the lens holding microcartridge provided with grooves in the passageway to facilitate folding the cartridge in a closed position.

Figure 33A is a front end elevational view of the nozzle of an alternative embodiment of the lens holding microcartridge.

Figure 33B is a front end elevational view of the nozzle of a further alternative embodiment of the lens holding microcartridge.

# DESCRIPTION OF PREFERRED EMBDODIMENTS

The present invention is directed to a system including methods and devices for implantation of deformable intraocular lens structures for surgical placement in the eye.

An inventive device according to the present invention comprises a holder having a receiver, a lens holder that can be removably inserted into the receiver of the holder, and means such as a moveable plunger disposed within the holder to force and manipulate the lens from the lens holder into the eye.

Preferably, the lens holder is defined by a lens holding microcartridge for receiving the lens structure. Further, the microcartridge is preferably a structure configured to be opened and closed. The preferred embodiment of the microcartridge receives a lens having prescribed memory characteristics when in the open position, and performs the function of folding or deforming the lens structure into a condensed configuration when being closed. Alternatively, the microcartridge can be a structure having a passageway defined by a continuous

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walled annulus, and a lens could be inserted into the passageway from the end of microcartridge by compressing, rolling, folding, or combination of these techniques prior to insertion into the microcartridge.

Once a lens is positioned into the microcartridge, the microcartridge is positioned into a plunger device. The assembled device maintains the lens in its condensed configuration during insertion into the eye yet permits the deformed lens to return to its original configuration, size and fixed focal length once implanted in the eye, thereby providing a safe, convenient, and comfortable surgical procedure.

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A preferred embodiment of a deformable intraocular lens implantation device 10 according to the present invention is shown in Figures 1, 2 and 3. The implantation device comprises a microcartridge 12 disposed within a holder 13 comprising a holder body 14 with a receiver 15, and a moveable plunger 16. In Figure 1, the receiver 15 is defined by an opening 17 through the wall of the holder body 14 of the size and shape shown in Figures 1 and 2. The opening 17 is defined by parallel edges 17a, 17a, which are sufficiently spaced apart to allow the microcartridge 12 to be loaded into the receiver 15 of the holder 13, tapered edges 17b, clamping edges 17c, and stop edge 17d. In Figure 1, the microcartridge 12 is positioned in the receiver 15 between the clamping edges 17c with the plunger extending through the microcartridge 12 in a position, for example, after a lens implantation procedure.

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In Figure 2, the lens holding microcartridge 12 is shown removed from the holder 13 with the plunger 16 in a retracted position for allowing the microcartridge 12 containing a loaded lens and its haptic to be inserted within the holder 13. In Figure 3, the holder 13 is shown with the plunger 16 in the extended position without the microcartridge 12 for purposes of illustration of the components.

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The plunger 16 is fitted with a threaded end cap 18 at one end, and fitted with a tip 20 at an opposite end. The threaded end cap 18 is provided with a plurality of grooves 22 to a allow a person to tightly grip the cap 18 with his or her finger tips. The threaded end cap 18 is received within a threaded sleeve 24 of the insert holder 14. The threaded end cap 18 can be a separate component attached to the insert holder 13, or integral therewith, as shown in the construction is Figure 5.

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The plunger 16 is installed within the holder 13 in a manner to allow the plunger to be reciprocated therein. In the illustrated embodiment, the plunger 16 is supported for sliding movement within the holder 13 by guide 26, as shown in Figures 5 and 6. The outer dimension of the guide 26 is approximately the same size as the inner dimensions of the holder 13 to allow the guide to be inserted within the insert holder. During construction, the guide 26 is inserted within the holder 13, and locked into position by pin 28 inserted into a predrilled hole in both the wall of the holder 13 and guide 26.

The cross-sectional shape of the plunger 16 as well as the shape of the inner surface of the guide 26 are approximately a half-circle, as shown in Figure 6. This arrangement prevents the plunger 16 from rotating within the holder 13 to maintain the orientation of the tip 20 relative to the holder 13 during operation.

The threaded end cap 18 is connected to the plunger 16 in a manner to allow the threaded end cap 18 to be rotated relative to the plunger 16. For example, the left end of the plunger 16 (Figure 5) is provided with a threaded extension 30, which is secured to the threaded end cap 18 by a nut 32. Specifically, the threaded end cap 18 is manufactured with

external threads 34 and a longitudinal center bore 36 that ends on the right side of the threaded end cap 18 leaving a wall 38.

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The wall 38 is provided with a hole slightly larger than the outer diameter of the threaded extension 34 to allow the threaded end cap 18 to freely rotate on the plunger 16 while being secured to the end of the plunger 16. During construction, the nut 32 is inserted through the center bore 36 and threaded onto the extension 30 to secure the threaded end cap 18 to the plunger 16. A curved cap 40 is press fitted into the end of the center bore 36 to seal the center bore 36 to prevent debris from entering therein during use.

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The details of the tip arrangement are shown in Figures 7 to 12. The plunger 16 is manufactured with an extension 42 supporting tip 20. The tip 20 structure provides means for inserting the deformable intraocular lens into the eye and manipulating the lens within the eye after the insertion step. For example, the tip 20 is faceted in the manner shown in the figures. Specifically, the left side of the tip 20 shown in Figure 8 is provided with a flat surface facet 42, conical surface 44, and cylindrical surface 46. The right side shown in Figure 11 is provided with a concave surface facet 50.

The end face of the tip 20 is designed to push the lens into position once inserted into the eye. For example, the end face is defined by a concave cylindrical surface 52 shown in Figure 8.

Suitable deformable intraocular lens for use in the present invention are shown in Figures 13 - 15. The deformable intraocular lens 54 shown in Figures 13 and 15 includes a lens body 56 with attachment means defined by a pair of haptics 58 each having one end anchored in the lens portion 56 and a free end for attachment to the eye tissue. The deformable intraocular lens 60 shown in Figure 14 includes a lens body 62 and attachment means defined by a pair of lateral lobes 64 of the lens portion 62.

The details of the preferred lens holding microcartridge 12 are shown in Figures 16 - 20. The microcartridge 12 comprises a split tubular member 66 extending to a continuous tubular member 67 and an implantation nozzle 68.

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When the microcartridge is in a closed position, a continuous circular or oval passageway of the same diameter extends through the split tubular member 66 through the continuous tubular member 67 and through the implantation nozzle 68. The microcartridge is preferably made of injection molded plastic such as The split tubular member 66 is defined by a fixed portion polypropylene 70 and a moveable portion 72. The fixed portion 70 is fixed relative to the implantation nozzle 68, and is defined by a tubular portion 74 and extension 72. The moveable portion 72 is moveable relative to the fixed portion 70 for opening and closing the split tubular member 66. The moveable portion 72 is defined by a tubular portion 78 and extension 80. A hinge 82 is provided between the fixed portion 70 and moveable portion 72. The hinge 82 is defined by reducing the thickness of the walls of the tubular portion 74 and 75 at the hinge 82, as shown in Figures 17, 18 and 19. The hinge 82 runs the length of the split tubular member 66 to allow the extension 76 and 78 to be split apart, or brought together to open and close, respectively, the split tubular member 66.

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The tubular portion 78 of the moveable portion 72 is provided with a sealing edge 84, which is exposed when the lens holding microcartridge 12 is opened, as shown in Figure 16A, and seals with a similar sealing edge 86 (See Figures 17 and 21) of the continuous tubular member 67 when the lens holding microcartridge is closed.

The end of the tip 20 is provided with three (3) equally spaced slots 87a, 87b and 87c of different length provided about the circumference thereof, as shown in Figures 20A and 20B. The slot 87a positioned at the top of the tip 20 is the shortest, slot 87c on the right side of the tip 20 is the longest, and slot 87b on the left side is of medium length. The slots 87a, 87b, 87c cause the lens 54 to rotate as it exits the tip 20.

Other embodiments of the microcartridge 12 according to the present invention are shown in Figures 30-33.

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The microcartridge shown in Figure 30 is provided with a beveled tip 94 to facilitate entry of the tip through the incision in the eye during implantation. The beveled tip 94 can be set at approximately forty-five (45) degrees relative to the passageway through the microcartridge 12.

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The embodiment of the microcartridge shown in Figures 31 and 32 is provided with a set of grooves 96 provided inside the passageway therethrough. The grooves accommodate the edges of the lens being loaded into the microcartridge to facilitate bending of the lens. Specifically, the edges of the lens are placed in the grooves 96 to prevent relative slippage of the edges with the inner surface of the passageway through the microcartridge when the microcartridge is being folded into the closed position.

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The embodiments of the microcartridge shown in Figures 33A and 33B each have a nozzle 68' having an oval cross-section with slots 87' differently position as shown, respectively, again to facilitate entry through an incision in the eye. Alternatively, the cross-section can be two half circles set apart and connected together rather than oval.

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The various features of the microcartridges shown in Figures 16-21 and 30-33 can be used in various combinations to achieved an optimum design for a particular application. However, all of these features are typically considered improvements of the basic combination.

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The components of the device 10, except for the microcartridge 12, are preferably fabricated from autoclavable material such as stainless steel or from a disposable rigid plastic such as medical grade ABS or the like.

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#### METHODS OF IMPLANTATION

The surgical procedure begins by coating the lens with a surgically compatible lubricant, and loading the lens into the microcartridge. For example, as shown in Figure 21, a lens 54 having a lens body 56, a leading haptic 58a is load into the microcartridge 12 while a trailing haptic 58b remains trailing outside the microcartridge in the manner shown. Specifically, the lens 54 is loaded downwardly into the opened microcartridge 12 until it sits on the inner surfaces of the tubular portions 74 and 78, for example, with a pair of tweezers. The outer circumferential surface of the lens 54 are held by edges 88 and 90 of the tubular portions 74 and 78, respectively. The rear edge of the lens 54 is placed approximately at the rear edge of the microcartridge 12. The lens 54 is further manipulated to situate the haptics 58a and 58b in the manner shown. Specifically, haptic 54a is positioned in a leading position and the other haptic 54b is positioned in a trailing position outside with respect to the direction of implantation, as indicated by the arrow.

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Subsequently, the split tubular member 66 of the microcartridge 12 is closed about the lens 54 by forcing the extensions 76 and 80 together with his or her finger tips. The inner surfaces of the tubular portions 74 and 78 bend and fold the lens 54 when the extensions 76 and 80 are forced together, as shown in Figures 22 and 23. Due to the resilient nature of the deformable intraocular lens 54, the lens 54 conform to the curved inner surface of the tubular portions 74 and 78 without damage thereto, as shown in Figure 23.

The microcartridge 12 containing the loaded lens 54 is inserted between the edges 17a, 17a of the opening 17 into the receiver 15 of the holder 13. As the microcartridge 12 is moved forward, the extensions 76 and 80 move past the tapered edges 17b and come to a stop position between the clamping edges 17c

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when front portions of the extensions 76 and 80 contact with the stop edge 17d. The clamping edges 17c prevent rotation of the microcartridge inside the holder 13.

The user pushes the threaded end cap 18 forward while securing the holder body 14 from movement, forcing the plunger 16 forward within the holder. As the plunger 16 is moved forward, the tip 20 enters into the rear of the microcartridge 12 and misses the trailing haptic 58B until the tip makes contact with the loaded lens 54, as shown in Figure 24. As the plunger 16 is moved forward in this manner, the lens 54 previously lubricated, is forced into the implantation nozzle 68 of the microcartridge 12, as shown in Figure 25.

Once the lens 54 enters the implantation nozzle 68, the threads of the end cap 18 contact with the threads of the sleeve 24 stopping further movement of the plunger 14 forward in this manner. The end cap 18 is slightly rotated to engage the threads of the end cap 18 with the threads of the sleeve 24. At this point, the surgical device is ready for the implantation step. The nozzle is insert through the incision in the eye, and the end cap 18 is rotated to continue the forward movement of the plunger 16 by continued rotation of the end cap 18 relative to the holder body 14 to expel the lens from the nozzle into the interior of the eye, as shown in Figure 26. This manner of screw advancement for moving the plunger 16 forward provides for precise control and accuracy concerning forcing the lens 54 through the remaining portion of the tip 68 into the eye during the implantation procedure. The deformed lens after exiting the nozzle 16 returns to its original configuration, full size and fixed focal length.

After the lens is inserted into the eye, the end cap 18 is further rotated to fully expose the tip 20 of the plunger 16, as shown in Figures 28 and 29, to allow the lens to be pushed forward, side manipulated to rotate the lens, and pushed down to properly position the lens within the eye without the aid of other surgical instruments.

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The configuration of the tip 20 is important during the implantation process. The faceted tip 20 provides a clearance between the tip 20 and the inner surface of the passageway through the microcartridge 12 to accommodate the trailing haptic 58b during movement of the lens within the microcartridge 12, as shown in Figures 25 and 26. Specifically, there exists a sufficient clearance between the flat surface facet 44 and the inner wall of the passageway through the microcartridge 12. During the implantation process, the trailing haptic floats around in the space between the extension 42 of the tip 20 and the inner wall of the passageway, as shown in Figure 25. This prevents any chance of damage to the trailing haptic, for example, by being caught between the tip 20 and the lens 54 during the implantation process. The leading haptic moves through the passageway unimpeded during the implantation process preventing any damage thereto.

Another embodiment of the present invention is shown in Figs. 34-38.

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The lens microcartridge 100 comprises a lens holding portion 102 and a nozzle portion 104. The lens microcartridge 100 is shown installed in a fixture 106 (e.g. end of implantation device 10) in Figs. 34, 35 and 36. The fixture 106 is basically a cylinder with a slot 108 having tapered edges 110 for guiding the lens microcartridge 100 into the fixture 106.

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The lens holding portion 102 is defined by a split tubular construction including a fixed tubular portion 112 and a moveable tubular portion 114. The fixed tubular portion 112 is provided with an extension 116 and the moveable tubular portion 114 is provided with an extension 118.

The important features of this embodiment include alignment means for aligning the extensions 116 and 118 when the lens microcartridge is closed, and means for tightly holding the lens microcartridge 100 closed when inserted in the fixture 106.

An example of means for aligning the extensions 116 and 118 when the lens microcartridge 100 is closed is an alignment groove 120 cooperating with an alignment nib 122, as shown in Fig. 37. The alignment groove 120 and alignment nib 122 extending the length of the extensions 116 and 118, respectively. However, it is not necessary the the alignment groove 120 and alignment nib 122 run the entire length of the extensions 116 and 118, and can still be effective is provided only for a portion of the length of the extensions.

Further, the alignment groove 120 and alignment nib 122 can be aligned with other extension alignment means such as male/female alignment tabs, protrusions, surfaces, etc. Maintaining the alignment of the extensions 116 and 118 when the len microcartridge is closed is important for maintaining the alignment of the moveable tubular portion 114 relative to the fixed tubular portion 112. This alignment of the tubular portions maintains the inner seams of the extensions 116 and 118 inside the passageway 124 in alignment preventing exposed edges of these seams that can cause damage to the deformable intraocular lens during loading and/or insertion operations, particularly during the transition of the deformable intraocular lens from the lens holding portion into the nozzle portion during the insertion operation.

Means means for tightly holding the lens microcartridge 100 closed when inserted in the fixture 106 can be provided by a varitey of structural features of both the fixture 106 and/or lens microcartridge 100.

Due to the slot 108 configuration of the fixture 106, means for wedging the extensions 116 and 118 together provides an inexpensive and effective manner of achieving the desired function.

For example, the extensions 116 and 118 can be provided with protrusions 126 and 128, respectively, that cooperated with the edges of the slot 108 of the fixture 106, as shown in Fig. 38. The protrusions 126 and 128 serve as means for wedging the extensions 126 and 128 tightly between the edges of the slot 108

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ensuring that the lens microcartridge is tightly held closed during the insertion operation. Further, the protrusions again provide means for also aligning the extensions 116 and 118 providing the benefit described above with respect to alignment of the extension 126 and 128 to prevent damage to the intraocular lens.

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The protrusions 126 and 128 resiliently, and possibly plastically deform to some extent during wedging utilizing the resilient properties of the plastic material of the lens microcartridge 100 to hold the lens holding portion 102 tightly closed and the extensions 116 and 118 accurately aligned.

The protrusions 126 and 128 can be in the form of strips, dots, squares or other shaped protrusions extending from the surfaces of the extensions 116 and 118.

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#### I CLAIM:

- 1. A lens microcartridge for use with a surgical device for implantation of a deformable intraocular lens into the eye through a relatively small incision made in the ocular tissue, said lens microcartridge comprising:
- 5 a lens holder portion;
  - a nozzle portion connected to and extending from said lens holder portion, said lens holder portion and said nozzle portion having a continuous passageway extending therethrough, said passageway having at least one groove extending along at least a portion of the length of said passageway for manipulating the deformable introcular lens as it passes through the lens microcartridge.
  - 2. A lens microcartridge according to Claim 1, wherein said groove varies in depth in a direction along the length of said passageway.
  - 3. A lens microcartidge according to Claim 2, wherein said groove tapers in depth in a direction along the length of said passageway.
- 4. A lens microcartridge according to Claim 3, wherein said groove tapers from deeper in said lens holder portion to shallower in said nozzle portion.
  - 5. A lens microcartridge according to Claim 1, wherein said passageway is provided with a set of opposed grooves extending along at least a portion of the length of said bore.
- 6. A lens microcartridge according to Claim 1, wherein at least one of said grooves varies in depth in a direction along the length of said passageway.

- 7. A lens microcartidge according to Claim 6, wherein said at least one groove tapers in depth in a direction along the length of said passageway.
- 8. A lens microcartridge according to Claim 7, wherein said at least one groove tapers from deeper in said lens holder portion to shallower in said nozzle portion.
- A lens microcartridge according to Claim 8, wherein both said grooves taper from deeper in said lens holder portion to shallower in said nozzle portion.
  - 10. A lens microcartridge according to Claim 9, wherein said grooves extend through a least a portion of said lens holder portion and said nozzle portion.
- 11. A lens microcartridge according to Claim 1, wherein said groove extends through a least a portion of said lens holder portion and said nozzle portion.
  - 12. A lens microcartridge according to Claim 1, wherein said lens holder portion and said nozzle portion define a one piece structure.
  - 13. A lens microcartridge according to Claim 1, wherein said nozzle portion includes a tapered end for facilitating entry of the nozzle portion through the incision in the ocular tissue.

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14. A lens microcartridge according to Claim 1, wherein said lens microcartridge is configured to open for loading the deformable intraocular lens into said lens lens microcartridge, and close for inserting said lens microcartridge into the device for implantation of the deformable introcular lens.

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15. A lens microcartridge according to Claim 14, wherein said lens microcartridge is configured to deform the deformable intraocular lens when closing to condense the configuration of the deformable intraocular lens to pass through said nozzle portion for implanting the lens through the incision in the ocular tissue.

- 16. A lens microcartridge according to Claim 15, wherein the deformable intraocular lens is placed into a curved folded configuration within said passageway in said lens microcartridge leading to said nozzle portion when said lens holder portion is closed.
- 17. A lens microcartridge according to Claim 16, wherein said lens holder portion comprises a split tubular member defining a portion of said passageway and connected to said nozzle portion, said split tubular member can be opened to insert the deformable intraocular lens and closed to insert the lens microcartridge into the device for implantation of the deformable introcular lens.
- 18. A lens microcartridge according to Claim 17, wherein said split tubular member is defined by a fixed tubular portion and a moveable tubular portion connected together at a hinge, said fixed tubular portion is connected to said nozzle portion and said moveable tubular portion moves relative to said nozzle portion.
- 20 19. A lens microcartridge according to Claim 18, wherein said hinge is defined by a decrease in wall thickness at a joint between said fixed tubular portion and said moveable tubular portion.

20. A lens microcartridge according to Claim 18, wherein said fixed tubular portion includes an extension and said moveable tubular portion includes an extension, said extensions are moved apart to open said lens holding portion for loading the deformable intraocular lens and moved together to fold the deformable intraocular lens and close said lens holding portion for inserting the lens microcartridge into the device for implantation of the deformable introcular lens.

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- 21. A lens microcartridge according to Claim 1, wherein the lens microcartridge is made of disposable surgically acceptable plastic.
- 22. A lens microcartridge according to Claim 1, wherein a cross section of said nozzle portion is one selected from the group of circular, oval and two half circles set apart and connected together.
  - 23. A lens microcartridge according to Claim 1, wherein a tip of said nozzle portion is provided with slots for allowing expansion of said passageway.
  - 24. A lens microcartridge according to Claim 1, wherein said passageway is provided with a pair of opposed grooves.
    - 25. A lens microcartridge according to Claim 1, wherein said lens holder portion is provided with grooves in said passageway therethrough to facilitate folding of the deformable intraocular lens being loaded.
- 26. A lens microcartridge according to Claim 24, wherein said lens holder portion is provided with grooves in said passageway therethrough to facilitate folding of the deformable intraocular lens being loaded.

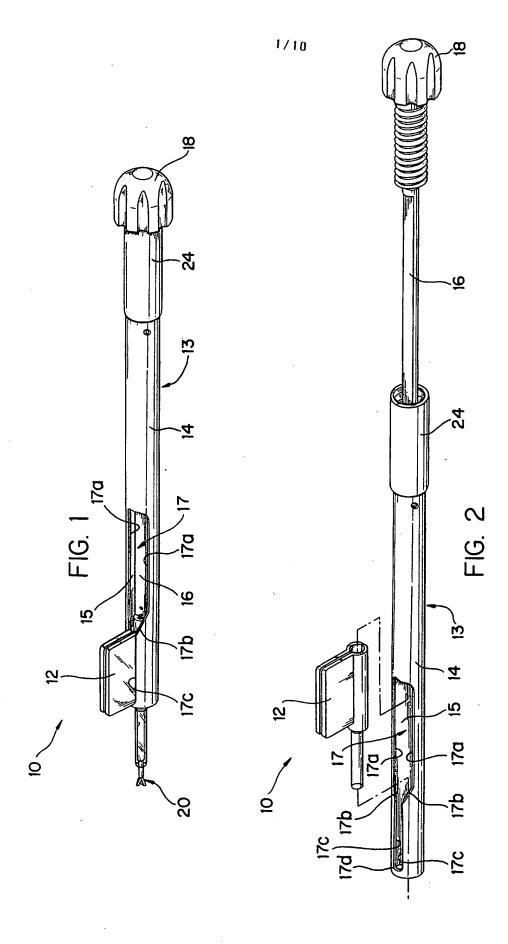
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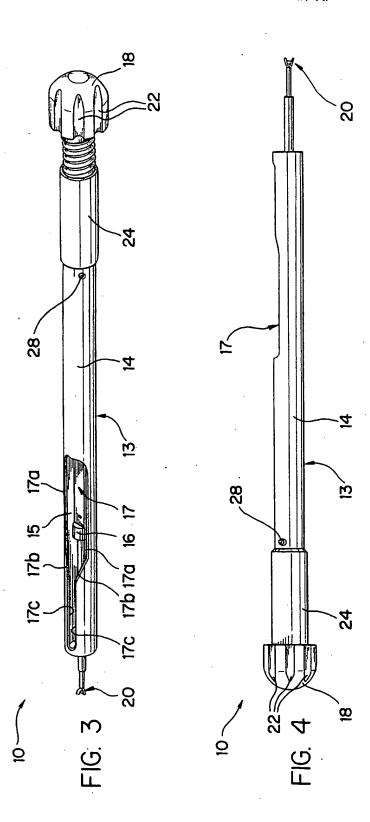
27. A lens microcartridge according to Claim 26, wherein said grooves in said lens holder portion for facilitating folding of the deformable intraocular lens define a portion of said pair of opposed grooves.

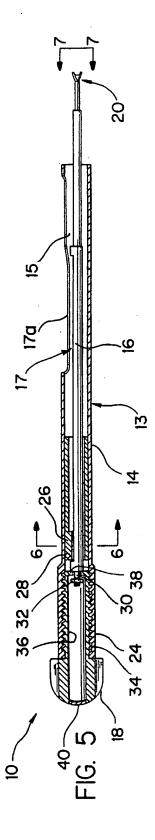
28. A lens microcartridge according to Claim 20, wherein said extensions are provide with alignment means for maintaining alignment of said extensions when said lens holding portion is closed.

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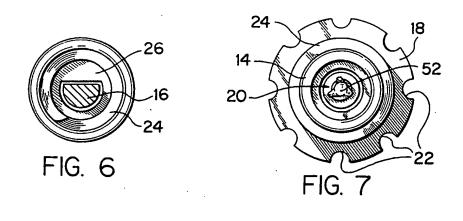
- 29. A lens microcartridge according to Claim 28, wherein said alignment means is defined by an alignment groove in one extension cooperating with an alignment nib in the other extension when said lens holding portion is closed.
- 30. A lens microcartridge according to Claim 29, wherein said alignment groove and said alignment nib extend the full length of said extensions.
  - 31. A lens microcartridge according to Claim 20, wherein the lens microcartridge is provided with means for tightly holding the lens microcartridge closed when installed in the device for insertion of the deformable intraocular lens.
  - 32. A lens microcartridge according to Claim 31, wherein said means for tighly holding the lens microcartridge closed is define by protrusions provided on said extension, said protrusions cooperating with surfaces of the device for insertion for wedging said extensions together.

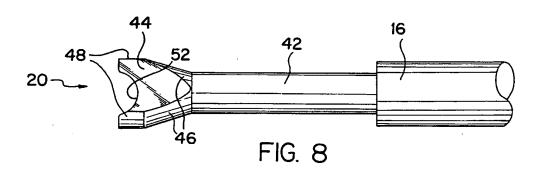


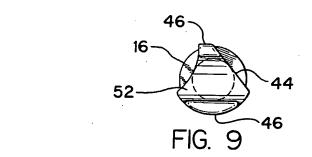


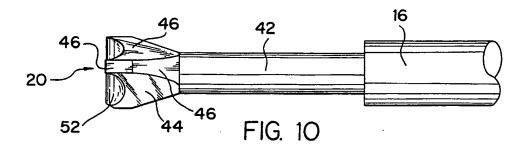


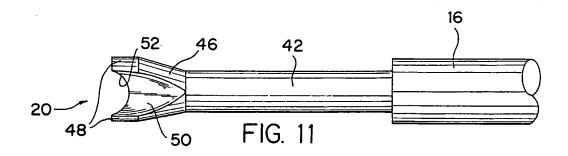
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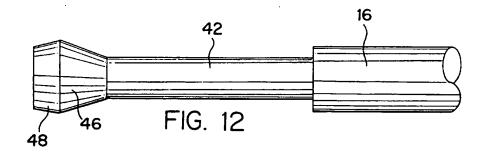


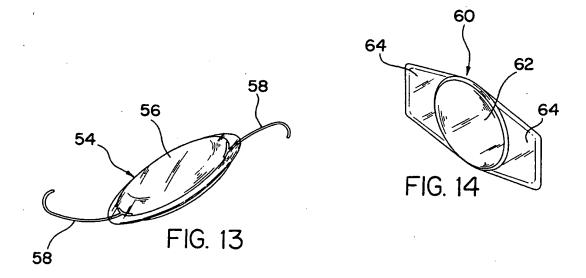


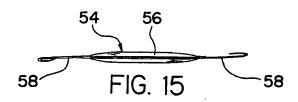


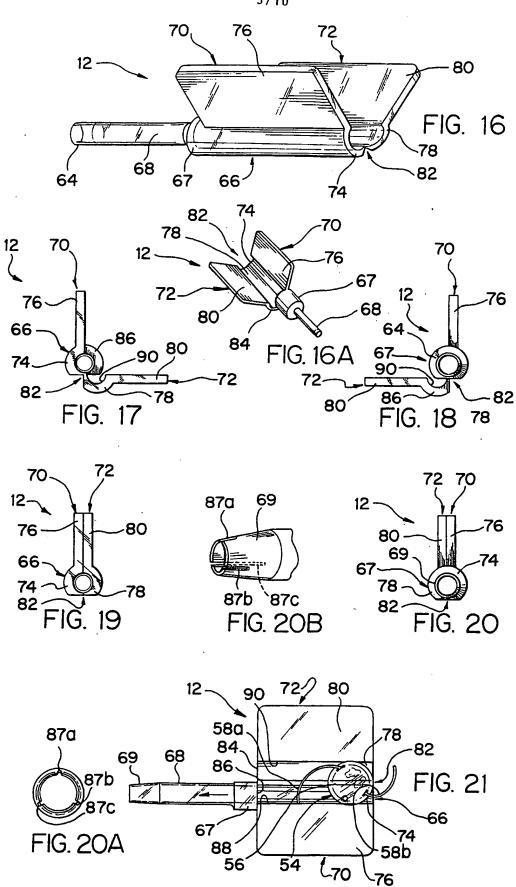




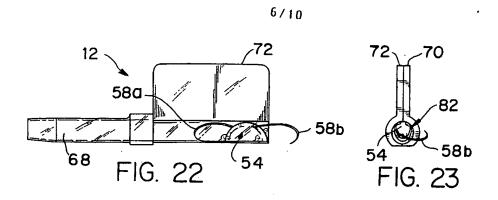


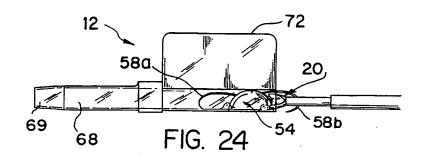


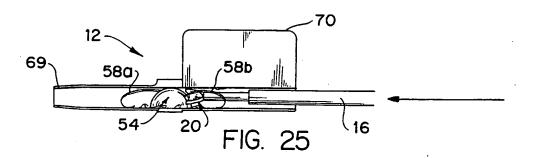


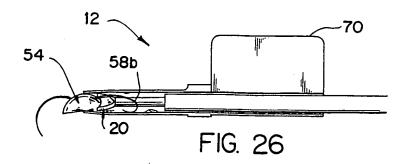


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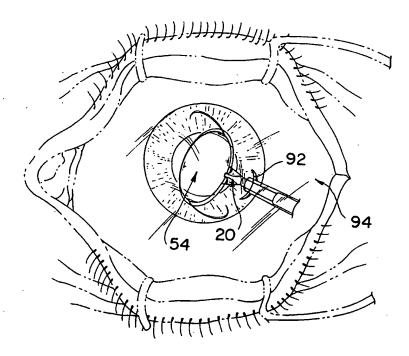


FIG. 27

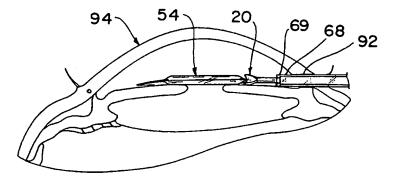
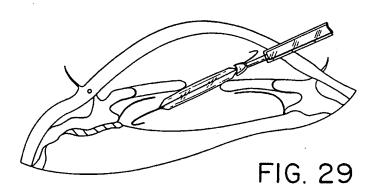
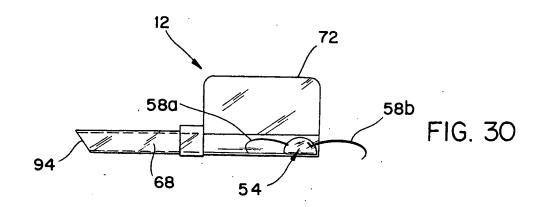
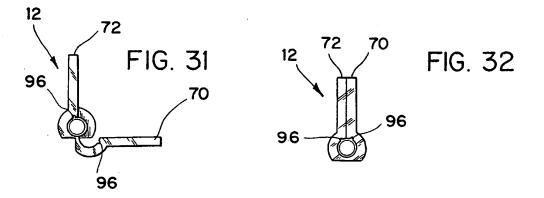
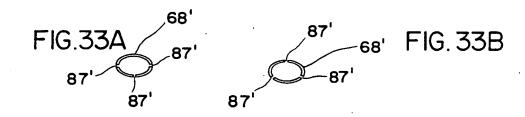


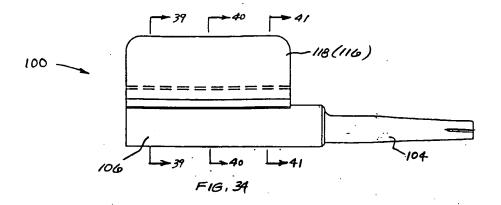
FIG. 28

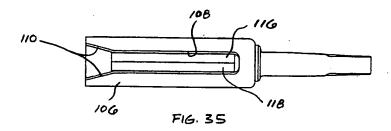


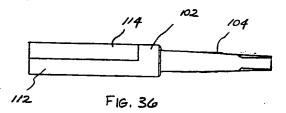












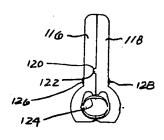
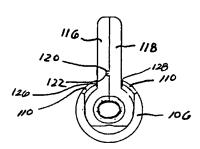
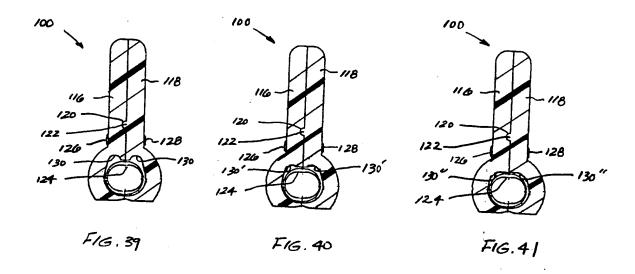


FIG. 37



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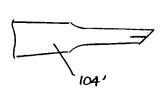


FIG. 42



FIG. 43

## INTERNATIONAL SEARCH REPORT

International application No. PCT/US95/02027

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| Category*  | Citation of document, with indication, where a   | ppropriate, of the relevant passages  | Relevant to claim No.  |  |  |  |
| X, P   | US, A, 5,275,604, (RHEINISH E  | TAL ) Od January 1994   | 1-16, 21, 22,  |  |  |  |
| ^ , '  | See Figs. 3 and 5.   | 1 AL.,, 04 Salidary 1994.   | 1-16, 21, 22,<br>24-27   |  |  |  |
|  |  | •   | 24-27  |  |  |  |
| A  | US, A, 4,702,244 (MAZZOCCO)  | 27 OCTOBER 1987, see  | 1-32   |  |  |  |
|  | Figures 37-49  |   |  |  |  |  |
|  |  | •   |  |  |  |  |
| Α  | US, A, 4,681,102, (BARTELL),   | 21 July 1987. See Figs. 2   | 1-32   |  |  |  |
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| Furth  | er documents are listed in the continuation of Box (   | See patent family annex.  |  |  |  |  |
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|  | nument published prior to the international filing date but later than priority date claimed     | *&* document member of the same patent  | family   |  |  |  |
| Date of the actual completion of the international search  Date of mailing of the international search report  |  |   |  |  |  |  |
| 19 MARCH 1995 03 APR 1995  |  |   |  |  |  |  |
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| Name and mailing address of the ISA/US Commissioner of Patents and Trademarks  Authorized officer  |  |   |  |  |  |  |
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| Furm PCT/ISA/210 (second sheet)(July 1992)*  |  |   |  |  |  |  |